

#### **Data & Statistics**

The United States has the safest, most effective vaccine supply in history. In the majority of cases, vaccines cause no side effects, however they can occur, as with any medication—but most are mild. Very rarely, people experience more serious side effects, like allergic reactions.

In those instances, the National Vaccine Injury Compensation Program (VICP) allows individuals to file a claim for financial compensation.

#### What does it mean to be awarded compensation?

Being awarded compensation for your claim does not necessarily mean that the vaccine caused the alleged injury. In fact:

- Over 80 percent of all compensation awarded by the VICP comes as result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.
- Attorneys are eligible for reasonable attorneys' fees, whether or not the petitioner is awarded
  compensation by the Court, if certain minimal requirements are met. In those circumstances,
  attorneys are paid by the VICP directly. By statute, attorneys may not charge any other fee,
  including a contingency fee, for his or her services in representing a petitioner in the VICP.

#### What reasons might a claim result in a negotiated settlement?

- Prior to a decision by the U.S. Court of Federal Claims, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The desire to resolve a case quickly

#### How many claims have been awarded compensation?

From 2006 to 2014, over 2.5 billion doses of covered vaccines were distributed in the U.S. according to the CDC. 3,255 claims were adjudicated by the Court for claims filed in this time period and of those 2,012 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 16,318 claims have been filed with the VICP. Over that 27 year time period, 14,189 claims have been adjudicated, with 4,277 of these determined to be compensable, while 9,912 were dismissed. Total compensation paid over the life of the program is approximately \$3.2 billion.

This information reflects the current thinking of the United States Department of Health and Human Services on the topics addressed. This information is not legal advice and does not create or confer any rights for or on any person and does not operate to bind the Department or the public. The ultimate decision about the scope of the statutes authorizing the VICP is within the authority of the United States Court of Federal Claims, which is responsible for resolving claims for compensation under the VICP.

# VICP Adjudication Categories, by Alleged Vaccine, For Claims Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006 Through 12/31/2014

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for	Number of Doses Distributed in the U.S., 01/01/2006	Co	ompensable		Compensable Total	Dismissed/Non- Compensable Total	Grand Total
compensation)	through						
DT	712,347	1		4	5	4	9
DTaP	83,052,184	13	19	81	113	81	194
DTaP-Hep B-IPV	51,305,397	4	7	18	29	38	67
DTaP-HIB	1,135,474					1	1
DTaP-IPV-HIB	46,401,211			7	7	12	19
DTap-IPV	15,490,820						
DTP	0	1	1	2	4	2	6
DTP-HIB	0			3	3	1	4
Нер А-Нер В	12,740,305			9	9	2	11
Hep B-HIB	4,787,457	1	1	1	3	1	4
Hepatitis A (Hep A)	136,935,713	6	3	23	32	22	54
Hepatitis B (Hep B)	143,946,953	2	11	47	60	39	99
HIB	93,160,376		1	4	5	5	10
HPV	77,506,945	11	1	71	83	92	175

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Influenza	1,078,000,000	91	91	1,024	1,206	193	1,399
IPV	62,344,612			4	4	2	6
Measles	135,660			1	1		1
Meningococcal	64,004,175	1	4	26	31	4	35
MMR	80,115,475	19	13	61	93	77	170
Mumps	110,749						
MMR-Varicella	14,403,057	8		8	16	8	24
Nonqualified	N/A			2	2	22	24
OPV	0	1			1	3	4
Pneumococcal	150,497,243		1	5	6	14	20
Conjugate							
Rotavirus	79,636,437	4	3	15	22	7	29
Rubella	422,548		1		1		1
Td	57,940,972	7	6	53	66	18	84
Tdap	177,160,298	28	6	109	143	18	161
Tetanus	3,836,052	4		23	27	11	38
Unspecified	N/A	1	1	3	5	556	561
Varicella	96,646,081	4	7	24	35	10	45
<b>Grand Total</b>	2,532,428,541	207	177	1,628	2,012	1,243	3,255

#### **Notes on the Adjudication Categories Table**

The date range of 01/01/2006 through 12/31/2014 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

In addition to the first vaccine alleged by a petitioner, which is the vaccine listed in this table, a VICP petition may allege other vaccines, which may form the basis of compensation.

Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type. Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

"Unspecified" means insufficient information was submitted to make an initial determination. The concession was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s) and the settlements were for multiple vaccines later identified in the Special Master's decisions.

#### **Definitions**

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Compensable – The injured person who filed a claim was paid money by the VICP. Compensation can be achieved through a concession by the U.S. Department of Health and Human Services (HHS), a decision on the merits of the claim by a special master or a judge of the U.S. Court of Federal Claims (Court), or a settlement between the parties.

- Concession: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision**: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).

For injury claims, compensable court decisions are based in part on one of the following determinations by the court:

- 1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
- 2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- Settlement: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Claims may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
- Non-compensable/Dismissed: The injured person who filed a claim was ultimately not paid money. Non-compensable Court decisions include the following:
  - 1. The Court determines that the person who filed the claim did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
  - 2. The claim was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).

3. The injured person voluntarily withdrew his or her claim.

## Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 10/01/2015

		Filed				
Vaccines	Injury Death Grand		Compensated	Dismissed		
			Total			
DTaP-IPV	3	0	3	0	0	
DT	69	9	78	25	51	
DTP	3,286	696	3,982	1,271	2,706	
DTP-HIB	20	8	28	7	21	
DTaP	390	79	469	188	205	
DTaP-Hep B-IPV	63	26	89	30	34	
DTaP-HIB	13	1	12	4	3	
DTaP-IPV-HIB	33	17	50	7	12	
Td	188	3	191	111	66	
Tdap	287	1	288	145	15	
Tetanus	100	2	102	49	37	
Hepatitis A (Hep A)	75	6	81	31	22	
Hepatitis B (Hep B)	626	54	680	251	364	
Нер А-Нер В	23	0	23	9	2	
Hep B-HIB	8	0	8	4	3	
HIB	31	3	34	12	15	
HPV	282	14	296	83	92	
Influenza	2,068	92	2,160	1,221	168	
IPV	264	14	278	8	267	
OPV	282	28	310	158	150	
Measles	143	19	162	55	107	
Meningococcal	45	2	47	31	4	
MMR	903	57	960	372	506	
MMR-Varicella	32	1	33	16	8	
MR	15	0	15	6	9	
Mumps	10	0	10	1	9	
Pertussis	4	3	7	2	5	
Pneumococcal	41	7	48	10	27	
Conjugate						
Rotavirus	69	1	70	40	18	
Rubella	190	4	194	70	123	
Varicella	82	7	89	54	20	
Nonqualified1	89	9	98	2	87	
Unspecified2	5,414	9	5,423	4	4,756	
<b>Grand Total</b>	15,146	1,172	16,318	4,277	9,912	

<sup>&</sup>lt;sup>1</sup> Nonqualified petitions are those filed for vaccines not covered under the VICP.

<sup>&</sup>lt;sup>2</sup> Unspecified petitions are those submitted with insufficient information to make a determination.

## **Petitions Filed**

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	633
FY 2015	802
Total	16,318

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed.

On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	232	294
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	82	123	205
FY 2008	147	132	279
FY 2009	134	231	365
FY 2010	180	293	473
FY 2011	266	1,371	1,637
FY 2012	263	2,439	2,702
FY 2013	367	628	995
FY 2014	371	167	538
FY 2015	449	77	526
Total	4,277	9,912	14,189

### **Awards Paid**

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	\$1,317,654.78	\$54,107.14	0	\$0.00	0	\$0.00	\$1,371,761.92
FY 1990	88	\$53,252,510.46	\$1,379,005.79	4	\$57,699.48	0	\$0.00	\$54,689,215.73
FY 1991	114	\$95,980,493.16	\$2,364,758.91	30	\$496,809.21	0	\$0.00	\$98,842,061.28
FY 1992	130	\$94,538,071.30	\$3,001,927.97	118	\$1,212,677.14	0	\$0.00	\$98,752,676.41
FY 1993	162	\$119,693,267.87	\$3,262,453.06	272	\$2,447,273.05	0	\$0.00	\$125,402,993.98
FY 1994	158	\$98,151,900.08	\$3,571,179.67	335	\$3,166,527.38	0	\$0.00	\$104,889,607.13
FY 1995	169	\$104,085,265.72	\$3,652,770.57	221	\$2,276,136.32	0	\$0.00	\$110,014,172.61
FY 1996	163	\$100,425,325.22	\$3,096,231.96	216	\$2,364,122.71	0	\$0.00	\$105,885,679.89
FY 1997	179	\$113,620,171.68	\$3,898,284.77	142	\$1,879,418.14	0	\$0.00	\$119,397,874.59
FY 1998	165	\$127,546,009.19	\$4,002,278.55	121	\$1,936,065.50	0	\$0.00	\$133,484,353.24
FY 1999	96	\$95,917,680.51	\$2,799,910.85	117	\$2,306,957.40	0	\$0.00	\$101,024,548.76
FY 2000	136	\$125,945,195.64	\$4,112,369.02	80	\$1,724,451.08	0	\$0.00	\$131,782,015.74
FY 2001	97	\$105,878,632.57	\$3,373,865.88	57	\$2,066,224.67	0	\$0.00	\$111,318,723.12
FY 2002	80	\$59,799,604.39	\$2,653,598.89	50	\$656,244.79	0	\$0.00	\$63,109,448.07
FY 2003	65	\$82,816,240.07	\$3,147,755.12	69	\$1,545,654.87	0	\$0.00	\$87,509,650.06
FY 2004	57	\$61,933,764.20	\$3,079,328.55	69	\$1,198,615.96	0	\$0.00	\$66,211,708.71
FY 2005	64	\$55,065,797.01	\$2,694,664.03	71	\$1,790,587.29	0	\$0.00	\$59,551,048.33
FY 2006	68	\$48,746,162.74	\$2,441,199.02	54	\$1,353,632.61	0	\$0.00	\$52,540,994.37
FY 2007	82	\$91,449,433.89	\$4,034,154.37	61	\$1,692,020.25	0	\$0.00	\$97,175,608.51
FY 2008	141	\$75,716,552.06	\$5,191,770.83	73	\$2,511,313.26	2	\$117,265.31	\$83,536,901.46
FY 2009	131	\$74,142,490.58	\$5,404,711.98	36	\$1,557,139.53	28	\$4,241,362.55	\$85,345,704.64
FY 2010	173	\$179,387,341.30	\$5,961,744.40	56	\$1,886,239.95	22	\$1,978,803.88	\$189,214,129.53
FY 2011	251	\$216,319,428.47	\$9,572,042.87	403	\$5,589,417.19	28	\$2,001,770.91	\$233,482,659.44
FY 2012	249	\$163,491,998.82	\$9,104,488.60	1,017	\$8,621,182.32	37	\$5,420,257.99	\$186,637,927.73
FY 2013	375	\$254,666,326.70	\$13,333,179.53	703	\$6,970,278.84	50	\$1,454,851.74	\$276,424,636.81
FY 2014	365	\$202,084,196.12	\$11,973,575.82	505	\$6,801,345.79	38	\$2,493,460.73	\$223,352,578.46
FY 2015	508	\$204,137,880.22	\$14,378,401.63	109	\$3,322,873.36	50	\$3,089,497.68	\$224,928,652.89
Total	4,272	\$3,006,109,394.75	\$131,539,759.78	4,989	\$67,430,908.09	255	\$20,797,270.79	\$3,225,877,333.41

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"Compensated" are claims that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/claims are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the claim, whether or not the petition/claim is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Due to the populations receiving vaccines added to the VICP in recent years, the proportion of adults to children seeking compensation has changed. Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult claims related to that vaccine have been filed.